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| EXAMINER | |
|---|---|
| CRAIG, PAULA L | |
| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/614,722 | MAIANTI ET AL. | |
| | Examiner | Art Unit | |
| | PAULA L. CRAIG | 3761 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,4 and 5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Arguments*

1. The rejection of Claim 3 is withdrawn as moot. As to the remaining claims, Applicant's arguments filed August 11, 2008 have been fully considered but they are not persuasive. Applicant argues that there is no basis or reason why a person of skill in the art would modify Ghelli in the particular manner required by Claim 1. Applicant argues that this conclusion is shown by the number of contentions regarding obviousness, as Claim 1 requires at least five features not disclosed in Ghelli. Regardless of the number of features not disclosed in Ghelli, all the claimed elements were known in the prior art; one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. *KSR International Co. v. Teleflex Inc.,* 82 USPQ2d 1385 (U.S. 2007). Ghelli teaches a compact pulsating pump unit, which may be used with a variety of other components to form a complete extracorporeal circuit system (Abstract, Figs. 1-5 and 7, paragraphs 1-3, paragraphs 7-8, 15, 24-27). Ghelli expressly teaches the system having a heat exchanger, followed in order by a pump and an oxygenation apparatus (Fig. 7, paragraphs 1-2, 8, 14-15, 21-27). Ghelli also teaches the system having a reservoir (paragraph 2). Applicant's specification teaches a variety of configurations, including some which include different pump types or connect up the components in an order different from that claimed (specification, Figs. 1-5, page 3, lines 24-30, page 4, lines

16-24, page 5, lines 13-14). For example, the embodiment of Fig. 3 has the pump 3 after the heat exchanger 4 as claimed; the embodiment of Fig. 5 has the pump 3 before the heat exchanger 4 (specification, page 3, lines 24-30, page 4, lines 16-24). No evidence, such as laboratory results, has been presented by the Applicant to show that the placement of the pump before the oxygenator or after the heat exchanger has any effect on the performance of the device. Applicant's specification also teaches that a system with the reservoir first, followed by the pump, the heat exchanger, the oxygenation apparatus, and an arterial blood filter, is known in the art (specification, Fig. 1, page 3, lines 10-18). See *In re Dailey and Eilers*, 149 USPQ 47 (CCPA 1966). Mather teaches that an arrangement with the reservoir first, followed in order by the heat exchanger, the pump, and the oxygenator as claimed, is preferred, but that an alternative arrangement with the oxygenator first, followed by the reservoir, the heat exchanger, and the pump respectively, and another arrangement with the reservoir first, followed in order by the heat exchanger, the oxygenator, and the pump, are also possible (Figs. 5-7, col. 6, line 42 to col. 7, line 5). This suggests that placement of components such as the reservoir at suitable locations in the system is within the ordinary skill in the art. U.S. Patent Application Publication No. 2004/0015042 to Vincent teaches a system having a pump at more than one point (see Fig. 12, paragraphs 50-51 and Claim 6 of Vincent; note that Vincent teaches pulsating pumps and that a pulsatile flow mimics the normal flow generated by a beating heart; paragraph 45).

2. For the arterial blood filter, the purpose of the filter is to prevent clots or other objects in the flow from reaching the patient; in light of this, it is obvious for the arterial filter to be located after the other components (see Raible, Fig. 9, col. 12, line 54 to col. 13, line 41col. 15, lines 17-24). Vincent also teaches an arterial blood filter 152 after the other components (Fig. 12, paragraph 51).

## *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. The rejections of Claims 1-2 and 4-5 under 35 U.S.C. 103(a) as being unpatentable over Ghelli (US 2002/0057990) in view of Mather (U.S. 4,424,190), and further in view of Raible (US 5,770,149), are maintained.

5. For Claim 1, Ghelli teaches a device for treating blood in an extracorporeal circuit having a reservoir and a heat exchanger having an inlet and an outlet (reservoir

includes reservoir bag; heat exchanger includes heat exchanger 11; Fig. 7, paragraphs 1-3, 8, 14, 24-27, Claim 19). Ghelli teaches a pulsating pump having an inlet connected to receive blood from the outlet of the heat exchanger, and an outlet (pumping unit 1, Fig. 7, paragraphs 1-3, 15 and 21-24). Ghelli teaches an oxygenation apparatus having an inlet and an outlet (oxygenation apparatus includes oxygenator 12; Fig. 7, paragraphs 2-3, 8, 24-27, Claim 19). Ghelli teaches a filter (paragraph 2). Ghelli teaches the integration of the heat exchanger, the pump, and the oxygenation apparatus into a single monolithic assembly to save space in the vicinity of the operating field (Fig. 7 and paragraphs 2-3, 24-27). Ghelli teaches blood flowing through an inlet of the heat exchanger 11; and the outlet of the pump being connected to the inlet of the oxygenation apparatus 12 (Figs. 1-7, paragraphs 1-3, 8, 17, 21-24, Claim 19). Ghelli does not expressly teach the reservoir being a venous blood reservoir with an inlet and an outlet; the outlet of the venous reservoir being connected to the inlet of the heat exchanger; the outlet of the oxygenation apparatus being connected to the inlet of an arterial blood filter; or the reservoir and filter being integrated into the monolithic assembly. Venous blood reservoirs well known in the art. The outlet of a venous reservoir being connected to the inlet of a heat exchanger, and the outlet of an oxygenation apparatus being connected to the inlet of an arterial filter, are well known in the art. Integration of components, including venous blood reservoirs and arterial blood filters, into a monolithic assembly is well known in the art of extracorporeal circuits. Mather confirms that a venous blood reservoir is well known, and teaches a venous blood reservoir 20 with an inlet 30 and an outlet 35, and a heat exchanger 40 having an

inlet and an outlet 62 (inlet of heat exchanger includes blood manifold 38; Figs. 1-5, col. 1, lines 7-20, col. 2, line 55 to col. 5, line 7, col. 6, lines 27-53; note that the reservoir of Mather includes a bag 24). Mather confirms that having the outlet 35 of a venous reservoir 20 connected to the inlet of the heat exchanger 40 is known, and teaches this configuration (Figs. 1-5, col. 3, lines 47-59, col. 6, lines 42-53). Mather teaches a pump having an inlet connected to receive blood from the outlet 62 of the heat exchanger 40, and an outlet (Fig. 5, col. 6, lines 42-53). Mather teaches an oxygenation apparatus 60 having an inlet 64 and an outlet 80 (Figs. 1-5, col. 3, lines 47-59, col. 6, lines 27-53). Mather teaches at least the reservoir 20, the heat exchanger 40, and the oxygenation apparatus 60 being integrated into a single monolithic assembly 10 (Figs. 3-5 and 9, col. 1, lines 7-20, col. 7, lines 12-29; note that in addition, all the components may be placed on movable console 100). In light of Ghelli's teaching of a reservoir and of blood flowing through an inlet of the heat exchanger, it would have been obvious to one of ordinary skill in the art for the outlet of a venous reservoir to be connected to the inlet of a heat exchanger, as taught by Mather. In light of Ghelli's teaching that a monolithic assembly saves space in the vicinity of the operating field, it would have been obvious to one of ordinary skill in the art for the reservoir to be integrated into the monolithic assembly, as taught by Mather. Raible '149 teaches a device for treating blood in an extracorporeal circuit including a venous blood reservoir having an inlet and an outlet (extracorporeal blood oxygenation system 10 and reservoir 111, Figs. 3 and 8-9a, col. 1, lines 7-13, col. 3, lines 55-62, col. 5, lines 18-38, col. 12, lines 8-52, col. 13, line 60 to col. 14, line 5). The device has an arterial blood filter having an inlet and an outlet (arterial filter

apparatus 128 and chamber 126, Figs. 9-9a, col. 3, line 63 to col. 4, line 4, col. 12, line 55 to col. 13, line 41, col. 15, lines 17-25). Raible teaches the outlet of an oxygenation apparatus being connected to the inlet of an arterial filter (oxygenation apparatus includes membrane oxygenator portion, gas-exchange cavity 72, and gas exchange membranes 74; arterial filter includes arterial filter apparatus 128 and chamber 126; Figs. 3 and 8-9a, col. 3, line 31 to col. 4, line 4, col. 8, line 1 to col. 9, line 17, col. 12, line 55 to col. 13, line 41, col. 15, lines 17-25). Raible teaches that the arterial blood filter allows the blood to be filtered before returning the blood to the patient (col. 3, line 62 to col. 4, line 4). Raible teaches both the venous blood reservoir and the arterial blood filter being integrated into a monolithic assembly (Figs. 8-9a, col. 12, line 6 to col. 13, line 41). Raible teaches that a single integrated structure allows the device to be positioned close to the patient, thereby minimizing the need for lengthy blood-filled tubes (col. 1, line 45 to col. 2, line 8). In light of Ghelli's teaching of a filter, it would have been obvious to one of ordinary skill in the art to modify Ghelli to include an arterial filter connected to the outlet of the oxygenation apparatus, as taught by Raible, to allow the blood to be filtered before returning the blood to the patient, as taught by Raible. In addition, in light of Ghelli's teaching that a monolithic assembly saves space in the vicinity of the operating field, it would have been obvious to one of ordinary skill in the art to modify the monolithic assembly of Ghelli to include a reservoir and an arterial blood filter, as taught by Raible, to allow the device to be positioned close to the patient and minimize the need for lengthy blood-filled tubes, as taught by Raible.

6. For Claim 2, Ghelli teaches a reservoir (paragraphs 1-3). Ghelli does not expressly teach the reservoir being a cardiotomy reservoir. However, cardiotomy reservoirs are well known in the art. Mather confirms this and teaches a cardiotomy reservoir (blood inlet 32 goes to cardiotomy reservoir; Figs. 1-2 and 4, col. 2, lines 27-30, col. 4, lines 39-45 ). In light of Ghelli's teaching of a reservoir, it would have been obvious to one of ordinary skill in the art to modify Ghelli to include the reservoir being a cardiotomy reservoir, as taught by Mather.

7. For Claim 4, Ghelli teaches the device including a first hollow cylindrical structure for containing the oxygenation apparatus 12, wherein the first hollow cylindrical structure is suitable to accommodate the heat exchanger 11, and wherein the first hollow cylindrical structure supports the pump 1 at a lower end face (Fig. 7, paragraph 24). Ghelli teaches a reservoir and a filter (paragraphs 1-3). Ghelli teaches the integration of the heat exchanger and the oxygenation apparatus into a hollow cylindrical structure to save space in the vicinity of the operating field (Fig. 7 and paragraphs 2-3, 24-27). Ghelli does not expressly teach the first hollow cylindrical structure supporting a venous blood reservoir, nor a second hollow cylindrical structure monolithically connected to the first hollow cylindrical structure suitable for containing the arterial blood filter. However, a hollow cylindrical structure including a venous blood reservoir is well known in the art. A hollow cylindrical structure suitable for containing an arterial blood filter is also well known in the art. Mather teaches a hollow cylindrical structure supporting a venous blood reservoir 20, together with a heat exchanger 40, with the venous blood reservoir at an upper end face of the hollow cylindrical structure

(Figs. 1-5, col. 3, lines 47-53, col. 6, lines 27-53). In light of Ghelli's teaching of a reservoir and of integrating the heat exchanger and oxygenation apparatus into a hollow cylindrical structure to save space in the vicinity of the operating field, it would have been obvious to one of ordinary skill in the art to modify Ghelli to include the reservoir at the upper end of the hollow cylindrical structure, as taught by Mather. Raible teaches a hollow cylindrical structure including an arterial filter and monolithically connected to the other components (arterial filter includes arterial filter apparatus 128 and chamber 126; Figs. 3 and 8-9a, col. 3, line 31 to col. 4, line 4, col. 8, line 1 to col. 9, line 17, col. 12, line 55 to col. 13, line 41, col. 15, lines 17-25). Raible teaches that the arterial blood filter allows the blood to be filtered before returning the blood to the patient (col. 3, line 62 to col. 4, line 4). In light of Ghelli's teaching of a filter and a hollow cylindrical structure, it would have been obvious to one of ordinary skill in the art to modify Ghelli to include an arterial blood filter in a hollow cylindrical structure monolithically connected to the other components, as taught by Raible, to allow the blood to be filtered before returning the blood to the patient, as taught by Raible.

8. For Claim 5, Ghelli teaches the device including a first hollow cylindrical structure which accommodates the heat exchanger 11 and supports the pump 1 so as to arrange in a coaxial and directly facing configuration the inlet and outlet of the heat exchanger 11 with the inlet of the pump 1 (Fig. 7, paragraph 24). Ghelli teaches a reservoir (paragraphs 1-3). Ghelli teaches the integration of the heat exchanger and the pump into a hollow cylindrical structure to save space in the vicinity of the operating field (Fig. 7 and paragraphs 2-3, 24-27). Ghelli does not expressly teach the reservoir being a

venous blood reservoir, nor the hollow cylindrical structure supporting the reservoir so that the outlet of the venous blood reservoir is arranged in a coaxial and directly facing configuration with the inlet of the heat exchanger. Mather teaches the reservoir being a venous blood reservoir 20, and the hollow cylindrical structure supporting the reservoir so that the outlet of the venous blood reservoir 20 is arranged in a coaxial and directly facing configuration with the inlet of the heat exchanger 40 (Figs. 1-5 and 9, col. 3, lines 47-53, col. 6, lines 27-53). In light of Ghelli's teaching of a reservoir, it would have been obvious to one of ordinary skill in the art to modify Ghelli to include the reservoir being a venous blood reservoir, and the hollow cylindrical structure supporting the reservoir so that the outlet of the venous blood reservoir is arranged in a coaxial and directly facing configuration with the inlet of the heat exchanger, as taught by Mather.

***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAULA L. CRAIG whose telephone number is (571)272-5964. The examiner can normally be reached on M-F 8:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paula L Craig
Examiner
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/Tatyana Zalukaeva/

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